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| 10/612,832 | 07/01/2003 | Harald Stein | 086035-000000US | 3864 |

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| EXAMINER | |
|---|---|
| YAO, LEI | |
| **ART UNIT** | **PAPER NUMBER** |
| 1642 | |

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/612,832 | STEIN ET AL. | |
| | Examiner | Art Unit | |
| | Lei Yao, Ph.D. | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2 and 4-30* is/are pending in the application.

4a) Of the above claim(s) *10,12-14 and 19-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-9,11,15-18 and 29-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of group I with species A1, antibodies, and species B2, enzyme, in the reply filed on 4/29/2005 is acknowledged.

Applicants argue that the restriction requirement is traversed insofar as it separates group I from group II. Applicant states that the restriction requirement is apparently premised on the position that the two groups have distinct structure, function and usage, but points out that the groups differ in the target bound. Applicant argues that the examiner has not shown that distinct structure, functions and uses of the two types of target bound require corresponding distinct structure, functions and uses of the claimed reagents. Applicant concludes that because it is the reagent that is being claimed rather than the target, and the reagents have similar functions and uses, it is submitted that Groups I and II should be examined together.

These have been considered, but not found persuasive. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The group I and II are two distinct inventions because they are drawn to two distinct reagents for different usage, which are involved in different method steps and modes of operation. The reagents in the two inventions have different classifications. Searching the function and structural characteristics of the reagents are not co-extensive in non-patent literature and US patent database, which would impose a serious search burden. For this reason, the restriction requirement is deemed to be proper and is adhered to. The requirement is therefore made **FINAL**.

Claim 3 has been cancelled. Claims 1-2 and 4-30 are pending. Claims 10, 12-14 and 19-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Claims 1-2, 4-9, 11, 15-18 and 29-30 are examined on the merits.

### *Specification*

Specification is objected to because the sections (b), (c), (f), (g), and (i) as exemplified below, are either missing or not correctly stated in the specification. Appropriate correction is required. See MPEP § 608 and the following guidelines:

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

### *Claim Objections*

Claims 1-2, 4-8 and16-17 are objected to for typographical error as "characterised". Amending the word in the claims to "characterized" would obviate this objective.

*Claim Rejections - 35 USC § 112*

**The following is a quotation of the second paragraph of 35 U.S.C. 112:**

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation of, " Reagent, characterised in that, in at least two spatially separated positions on a cell-bound or soluble molecule" and "it enters into interactions with the latter or the nucleic acid coding for this".

A. It is not clear what the meaning of "two spatially separated positions on a cell-bound or soluble molecule" is. It is not clear whether the "cell-bound or soluble molecule" applies to the structure of the reagent or the structure of the target. It is unclear whether the structure is an antibody or an antigen. For purpose of examination, the description of two spatially separated positions on a cell-bound or soluble molecule will be applied to the target of the reagent rather than the reagent.

B. It is not clear what the meaning of "it enters into interactions with the latter or the nucleic acid coding for this" because it is unclear what the "latter" is referring to. For purpose of examination, the "later" will be interpreted as two spatially separated positions on a cell-bound or soluble molecule.

**The following is a quotation of the first paragraph of 35 U.S.C. 112:**

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Drawn to written description:**

Claims 1-2, 6, 8, 9, 11, 15-16 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was

not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-2, 4, 6, 8, 9, 11, 15-16 and 29-30 are inclusive of a genus of "reagent", which is characterized to have a target of "two separated positions on a cell-bound or soluble molecule" and "latter or the nucleic acid coding for this". However, the written description in this case only set forth an antibody binding to a core domain, CEPDY, of CD30 protein and the claims do not limit any particular conserved structural attributes for the reagent.

The specification discloses that the reagent of the invention is suitable for use in tumor-diagnosis and therapy of inflammatory diseases (page 4). The specification also discloses that the reagent covers one antigen domain as occurs with antibodies and antibody fragments (page 5). However, The written description only reasonable conveys one species of monoclonal antibody for CD30, which specifically bind to sequence of "DCRKQ**CEPDY**YLD and GDCRKQ**CEPDY**YL" of CD30 by epitope mapping and **CEPDY** as a core sequence (page 15, paragraph 2 and figure 3). The instant claims encompass significant structural and functional dissimilarity as compared to the monoclonal antibody binding to sequence CEPDY of CD30 because the term "reagent" encompasses any type of protein binding molecules, which need not originate from an immune response, as well as organic molecules, which include drugs not having a protein structure. Therefore, the monoclonal antibody binding to the core sequence CEPDY of CD30 does not anticipate the claimed genus because the genus includes molecules, which differ widely in structural attributes from antibody binding to CEPDY of CD30. Thus, one skill in the art cannot envision the detailed chemical structure of the encompassed "reagent".

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claimed reagent is one antibody, which binds to a core epitope of CD30. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features

common the genus that "constitute a substantial portion of the genus. Although drawn to DNA arts, the finding in University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) is relevant to the instant claims. The Federal Circuit addressed "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of reagents that encompass the genus of reagents that characterized to have targets of two spatially separated position on a cell-bound or soluble molecule and interaction with the latter or the nucleic acid coding for this, nor does it provide a description of structural features that are common to the reagent. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variants, the disclosure of the antibody to an epitope of CD30 is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of reagent, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The

compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only the antibody to the epitope **CEPDY** of CD30, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

**Drawn to deposit:**

Claims 7, 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel biologic materials, specific chimerized CD30 antibody as produced by the stored cell line DSZ1 (DSZ1 antibody) Since biological materials are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. However, the specification does not disclose a repeatable process to obtain the biological material and it is not apparent. If the biological materials are not so obtainable or available to the public, the requirement of 35 USC 112 may be satisfied by deposit of the biological material.

**Applicant's referral to the deposit antibody of CD30 as DSZ1 on page 8, paragraph 1 of the specification is s an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 have been met. There is no indication as to the public availability.**

If deposits are made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney or record who has the authority and control over the conditions of deposit over his/her signature or registration number stating that the deposit has been accepted by an International Depository authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed from the depository as required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. If deposits are not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring, showing that:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 CFR 1.807) and

(e) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Applicant's attention is directed to In re: Lundak, 773 F. 2d.1216, 227 USPQ 90 (CAFC 1985) and 37 CRF 1.801-1.809 for further information concerning deposit practice.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Gravekamp et al., (Infec and immu, vol 64, page 3572-3583).

Due to the indefinite nature of the claims (see USC 112 2$^{nd}$ above), for art purposes the claims 1-2 are interpreted, as written, to be a reagent, characterized as a molecule interacting with a protein or antigen, which comprises two spatially separated positions on a cell-bound or soluble molecule and the reagent coves at least one antigen binding domain.

Gravekamp et al., disclose a soluble protein (alpha C protein), which has at least of two repeats of units located in spatially separated positions (page 3578). Gravekamp et al., disclose antibodies, which interact with the repeating units spatially separated in the protein (page 3579 column 2).

Claims 1-2, 4-6, 15 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemke et al., (US Patent NO: 6033876).

Claims 1 and 2 are set forth above. Claims 4 and 6 embody the claim 1, wherein the reagent binds to core sequence of CD30 and reagent is chimerized antibody or a fragment. Claim 5 embodies the claim 1, wherein the reagent binds to an epitope with the core sequence CEPDY. Claim 15 is drawn to a cell to produce an antibody. Claims 29-30 are drawn to a pharmaceutical composition and a kit containing the antibody.

Lemke et al., disclose anti-CD30 antibodies. Lemke et al., the antibodies bind to CD30 antigen (section 2, line 39-40). Lemke et al., also disclose that the antibodies can be used as whole monoclonal antibodies, fragments (FV, (FV)2, Fab, Fab', or F(ab)2), chimeric, humanized (section 4, line 55). Lemke et al., further disclose cells, which produce CD30 antibodies (section 12, lien 17-22), process of making and testing the antibodies, as well as the antibody fragments (section 12 –13). Lemke et al., further disclose that the CD30 antibodies specifically bind to neoplasm, Hodgkin's disease cells (section 2, lien 14-28).

Although Lemke et al., do not disclose pharmaceutical composition and kit containing the antibody, claims 29-30 are anticipated by Lemke et al. See MPEP 2112.01-III as following:

> Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. In re Ngai, ___ F.3d ___, 2004 WL 1068957 (Fed. Cir. May 13, 2004.

Lemke et al do not specifically disclose that the antibodies bind to two spatially separated positions on cell-bound or soluble CD30. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 1 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated Mohler et al., (US Patent Application Publication NO: 20020064527).

Claims 1 and 5 are set forth above.

Mohler et al., disclose polyclonal antibodies, which are against to CD30 antigenic polypeptides (section 50-55). It would be reasonable to conclude that the antibodies include the antibody, which specifically bound to the core sequence CEPDY of CD30. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 1,5, 8-9 and 15-16 are rejected under 35 U.S.C. 102(e) as being anticipated Francisco et al., (US Patent Application Publication NO: 20040018194).

Claims 1 and 5 are set forth above. Claims 8-9 embody the claim 1, wherein the reagent is characterized to contain a linked peptidically with enzymes. Claims 15-16 are drawn to a cell, which contains a recombinant DNA coding for the reagent or a part.

Francisco et al., disclose that anti-CD30 antibodies are fused to proteins comprising a pro-drug converting enzyme (section 46).

Francisco et al., disclose anti-CD30 antibodies, which comprise a recombinant antibody. Francisco et al., disclose that recombinant cells, which contain a DNA encoding a heavy or light chain of any of the anti-CD30 antibodies (section 0074). Francisco et al., further disclose method of producing the anti-CD30 from the cells (section 0075).

Francisco et al., do not specifically disclose that the anti-CD30 antibodies bind to two spatially separated positions on cell-bound or soluble CD30. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not

possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 8-9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemke et al., in view of Deonarain et al., (Br J Cancer, vol 70 page 786-94, 1994).

Claims 1 and 8-9 are set forth above. Claim 11 embodies the claim 9, wherein the reagent is linked with enzymes from the group of the phosphodiesterases.

Lemke et al., teach that anti-CD30 antibodies, which bind to CD30 antigen on the cell of Hodgkin's disease (section 2, line 39-44).

Lemke et al., do not teach the anti-CD30 antibodies are linked to enzymes of phosphodiesterases.

Deonarain et al., teach that ribonuclease (RNas), an enzyme from group of phosphodiesterases, and using the enzyme for cancer therapy. Deonarain et al., also teach that RNase is fused to anti-tumor antigen antibody fragment, scFv. Deonarain et al., further teach that the fusion protein is cytotoxic to the cells at low concentrations (page 792, column 1, paragraph 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teaching of Lemke et al., on anti-CD30 antibody with the teaching of

Deonarain et al., on fusing the antibody with RNase. One of ordinary skill in the art would have been motivated to use the teachings of Lemke et al., and Deonarain et al., for linking the antibody for CD30 with RNase for the cancer treatment because Lemke et al., have shown the antibody bind to CD30 antigen on the cell of Hodgkin's disease and Denarain et al., have shown that a antibody fused with Rnase is cytotoxic to cells, One of skill in the art at the time of invention would have a reasonable expectation of success in fusing the CD30 antibody with RNase.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Dowining for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

Karen A. Canella

KAREN A. CANELLA PH.D
PRIMARY EXAMINER